



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

National Institute of Neurological Disorders and Stroke Federal Interagency Traumatic
Brain Injury Research (FITBIR) Data Access Request

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on July 8, 2016, page 44644 (81 FR 44644) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESS: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Sophia Jeon, Health Science Policy Analyst, Office of Science Policy and Planning (OSPP), NINDS, NIH, 31 Center Drive, Building 31, Room 8A03, Bethesda, MD 20892, or call non-toll-free number (301) 435-7571, or E-mail your request, including your address to: sophia.jeon@nih.gov

SUPPLEMENTARY INFORMATION: The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: National Institute of Neurological Disorders and Stroke Federal

Interagency Traumatic Brain Injury Research (FITBIR) Data Access Request, 0925-0677, Expiration Date 08/31/2016 – REINSTATEMENT with change, National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH).

Need and Use of Information Collection: The FITBIR Informatics System Data Access Request form is necessary for “Recipient” Principal Investigators and their organization or corporations with approved assurance from the DHHS Office of Human Research Protections to access data or images from the FITBIR Informatics System for research purposes. The primary use of this information is to document, track, monitor, and evaluate the use of the FITBIR datasets, as well as to notify interested recipients of updates, corrections or other changes to the database. Type of respondents affected by this information collection are researchers, such as Principal Investigators (PI), who are interested in obtaining access to study data and images from the FITBIR Informatics System for research purposes.

There are two scenarios for completing the form. The first is where the Principal Investigator (PI) completes the entire FITBIR Informatics System Data Access Request form, and the second where the PI has the Research Assistant begin filling out the form and PI provides the final reviews and signs it. Burden for this collection of information is estimated to vary from 30-95 minutes per response. The estimated annual burden hours to complete the data request form are listed below.

OMB approval reinstatement is requested for 3 years. The total estimated annualized burden hours are 63.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
FITBIR Informatics System Data Access Request	Individuals (Principal Investigators)	40	1	95/60	63

Dated: September 12, 2016

Paul Scott, PhD

Project Clearance Liaison Officer,

National Institute of Neurological Disorders and Stroke, NIH

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